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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,781	04/12/2007	Sean Farmer	19374-515 NATL	5510

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
01/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,781	FARMER ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-61 and 77-79* is/are pending in the application.

4a) Of the above claim(s) *53-58 and 77-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group II, claims 59-61 on 9/19/08 is acknowledged.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claims 59-61 are being considered on the merits. Claims 53-58 and 77-79 are withdrawn from consideration as directed to a non-elected invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 17-20, and 30-32 of copending Application No. 11/985617. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the copending applications are directed to the treatment of substantially similar symptoms in patients having or at risk of having digestive distress due to unidentified causes attributed to various conditions with substantially similar compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer *et al.* (WO 99/49877) taken with Eisenhardt *et al.* (U.S. Patent No. 6,410,018)

The claims are directed to a method of increasing lactose digestion by administration of *B. coagulans* and lactase.

Farmer *et al.* teach a method of administering *B. coagulans* for its many favorable probiotic effects and specifically to reduce cholesterol by administration of *B. coagulans* and other therapeutically useful agents. The addition of supplemental lactase to the composition of *B. coagulans* to be administered is taught at page 22, lines 5-9.

The reference differs from the claimed invention in the explicit increase in lactose digestion by use of *B. coagulans* and lactase. However, Eisenhardt *et al.* disclose that at least the administration of a lactase enzyme is recognized to increase lactose digestion. The reference discloses the use of about 7000 to about 35,000 neutral lactase units, which appears to be within the range as claimed. See, e.g., col. 5, lines 5-25 and Example..

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in increasing lactose digestion in patients suffering from or at risk of developing lactose intolerance upon growing older by using a probiotic *B. coagulans* that is recognized in the art to be highly resistant to adverse environments such as being bile resistant and resistant to gastric acid and known to be an effective producer of lactase as taught by Farmer '877.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to increase lactose digestion in people at risk of developing lactose intolerance by providing a probiotic *B. coagulans* that is recognized in the art to be highly resistant to adverse environments such as being bile resistant and resistant to gastric acid and known to be an effective producer of lactase as taught by Farmer '877 alone or in conjunction with lactase as suggested by the teachings of Eisenhardt *et al.* for the expected benefit of increasing lactose digestion in patients suffering from or at risk of developing lactose intolerance upon growing older and also lessening unpleasant symptoms such as gas, bloating and general intestinal discomfort.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Claims 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mustapha *et al.* taken with Eisenhardt *et al.* (U.S. Patent No. 6,410,018), Farmer *et al.* (I) (1997), Farmer *et al.* (II) (1998), and Long *et al.*.

The claims are directed to a method of increasing lactose digestion by administration of *B. coagulans* and lactase.

Mustapha *et al.* teaches the *in vivo* consumption of *Lactobacillus* to increase lactose digestion in patients suffering from or at risk of developing lactose intolerance. See, e.g., page 1539 and 1543 for identification of lactose maldigesters and page 1544, paragraph 2 for discussion of properties required for a suitable microorganism, such as being an effective β-galactosidase (lactase) producer and be resistant to gastric acid and the intestinal environment. See, e.g. Table 4, for the inclusion of diarrhea as a symptom which improves with the administration of the probiotic.

In addition, Eisenhardt *et al.* disclose that at least the administration of a lactase enzyme is recognized to increase lactose digestion. The reference discloses the use of about 7000 to

about 35,000 neutral lactase units, which appears to be within the range as claimed. See, e.g., col. 5, lines 5-25 and Example..

Farmer *et al.* (I) disclose the advantageous properties of *B. coagulans* for probiotic administration in the treatment of high cholesterol, for example, such as resistance to high heat, high pressure, and salty environments. See, e.g., Farmer *et al.* (I), page 6, paragraphs 2-3. In addition, Farmer *et al.* (II) adequately demonstrates that *B. coagulans* Hammer is also known as *Lactobacillus sporogenes* and is resistant to stomach acids and other digestive enzymes and moves through the intestines without loss of viability (See, e.g., page 41, col. 1 and 2).

In addition *B. coagulans* is recognized in the art to be an effective producer of lactase, as adequately demonstrated by Long *et al.* (See, e.g., col. 3.). Therefore, one of ordinary skill in the art would have recognized the presence of the supplementary enzyme lactase upon growth of the microorganism in the gastrointestinal tract

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in increasing lactose digestion in patients suffering from or at risk of developing lactose intolerance upon growing older by substituting the strain of Mustapha *et al.* with a known strain of the probiotic *B. coagulans* (*Lactobacillus sporogenes)* recognized in the art to be highly resistant to adverse environments such as being bile resistant and resistant to gastric acid and known to be an effective producer of lactase.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of increasing lactose digestion in people at risk of developing lactose intolerance as taught by Mustapha *et al.* of using a lactase producing strain of the probiotic *Lactobacillus acidophilus* by substituting therefor a strain of *B. coagulans (Lactobacillus sporogenes)* recognized in the art as being a suitable probiotic, resistant to environmental insults in the gastrointestinal tract, as taught by Farmer (I) and (II) as well as an efficient producer of lactase, as taught by Long *et al.*, alone or in conjunction with a lactase enzyme as suggested by the teachings of Eisenhardt *et al.* for the expected benefit of increasing lactose digestion in patients suffering from or at risk of developing lactose intolerance upon growing older and also lessening unpleasant symptoms such as gas, bloating and general intestinal discomfort.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the

absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651